UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF IDAHO

JEFFREY D. CONNELL and JANET CONNELL, husband and wife,

Plaintiffs,

v.

LIMA CORPORATE; LIMA USA, INC., an Indiana corporation; and JOHN DOE CORPORATIONS I through V,

Defendants.

Case No. 1:16-CV-00456-CWD

MEMORANDUM DECISION AND ORDER

INTRODUCTION

Six motions are pending before the Court: Lima Defendants'[1] two motions to exclude certain evidence (Dkts. 97 and 106), and motion for summary judgment (Dkt. 104), as well as Connell Plaintiffs' motion to exclude certain evidence (Dkt. 73), motion for partial summary judgment (Dkt. 98), and motion for leave to amend the complaint to add a claim for punitive damages. (Dkt. 99.) All six motions are fully briefed, and the Court heard oral argument on each motion from the parties on January 22, 2019. After careful consideration of the record, the parties' briefing and oral argument, as well as relevant authorities, the Court will grant Defendants' motion for summary judgment.

[1] The Court's discussion and decision applies only to Lima Corporate S.p.a. Lima USA, Inc. was dismissed from the case via previous order of the Court. (See Dkt. 132.)

BACKGROUND

In April of 2011, Plaintiff Jeffrey Connell underwent a total hip revision surgery at Saint Alphonsus Medical Center in Boise, Idaho. (Dkt. 1-6 at 3.) Plaintiff Janet Connell is his wife. Id. at 1. During the surgery Dennis McGee, M.D. implanted a femoral stem prosthesis. Id. at 3. The device implanted in Mr. Connell was sold to St. Alphonsus by Rose & Associates, a medical device distribution company. (Dkt. 59 at 4.) Rose & Associates contracted with DJO Surgical to distribute hip prosthesis systems in Idaho and other states. Id. at 3. The hip system implanted into Mr. Connell consisted of three parts: a revision hip stem, a femoral neck, and a safety screw. (Dkt. 113-3.) As discussed in detail below, the two main parts of the hip system, the stem and the neck, were manufactured in Italy by Defendant Lima Corporate S.p.a. (Lima). (Dkt. 112-1 at 3.)

At the time of his revision surgery, Mr. Connell was 49 years of age, approximately 6 feet tall, weighed 217 pounds, and had a Body Mass Index (BMI) in excess of 28. (Dkt. 59 at 5.) X-rays of Mr. Connell taken prior to his revision surgery showed he had proximal bone loss in his femur. (Dkt. 104-22 at 2).

In October of 2014, the femoral stem portion of Mr. Connell's hip prosthesis fractured while he was performing his work as a plumber—just three and one half years after implantation. (Dkt. 1-6 at 3.) Doctors at the University of Utah removed the failed hip prosthesis and implanted a different type of hip system. Id. at 3-4. The failed hip prosthesis was discarded after it was removed. (Dkt. 104-2 at 7.)

DJO produced a Product Complaint Report after investigating the fracture incident. (March 26, 2015 report, Dkt. 113-5.) According to DJO's report, the definitive root cause of the stem fracture could not be determined at that time because the hip stem was discarded and thus not available for inspection or testing. Id. at 3.

On August 9, 2016, Jeffery and Janet Connell filed a complaint against Lima Corporate, Lima USA, Inc., and the DJO entities. (Complaint, Dkt. 1-6.) Plaintiffs asserted product liability claims under Idaho law based in strict liability, negligence, and breach of warranty, as well as a claim of negligent infliction of emotional distress against all defendants. Id. In July of 2018, the DJO entities and Plaintiffs reached a settlement and filed a joint motion to dismiss all claims against the DJO entities. (Dkt. 62.) The settlement prompted a period of hard-fought discovery, concluding with the Court granting Plaintiffs' and DJO entities' motion to dismiss in November of 2018. (Dkt. 95.) As a result, the Lima entities became the only remaining defendants in this matter.

On November 19, 2018, Lima filed the present motion for summary judgment, arguing, primarily that, because it was a component supplier of medical device parts for DJO's hip system, all claims against Lima are preempted by the Biomaterials Access Assurance Act (BAAA). 21 U.S.C. Section 1604 et seq. However, as noted above, numerous motions are currently pending before the Court. The motions include Plaintiffs' motion for partial summary judgment on Lima's affirmative defense of comparative fault as to Dr. McGee and DJO (Dkt. 98), as well as a motion to amend the complaint to add a claim for punitive damages. (Dkt. 99.) The other motions are evidentiary in nature

whereby the parties seek to exclude certain evidence from trial. (Dkts. 73, 97, and 106.) Although the Court carefully considered the parties' briefing and arguments on all of these motions, the Court will first analyze the merits of Lima's motion for summary judgment based on BAAA preemption. As such, the facts that follow relate specifically to whether the BAAA so applies.

1. 2009 Supply Agreement

In April of 2009, Encore Medical, doing business as DJO Surgical, entered into a written supply agreement with Lima. (Dkt. 103-3.) According to the agreement's terms, as the "Seller," Lima agreed to supply to DJO, the "Purchaser," with "parts … used in or incorporated into a joint prosthesis system, including without limitation, the Components and Instruments, all in accordance with the terms and conditions" of the agreement. Id. at 4. The agreement described the Seller as being "engaged in the design, development, manufacture, distribution and sale of, among other things, the Components … for use in, among other things, total joint replacement systems." Id. Whereas the agreement described the Purchaser as being, "engaged in the design, development, manufacturing, distribution and sale of, among other things, joint prosthesis systems." Id.

The agreement defines Components as "parts developed and/or manufactured by Seller and designed for incorporation into joint prosthesis systems." Id. at 27. "Revision Modular Stems" are included within the agreement's list of Components. Id. at 36. The agreement describes a revision stem as being "made up of two components, a diaphyseal stem and a femoral neck." Id. at 31. The agreement provided that Lima was to

manufacture stems in six different diameters and two different lengths. Id. Likewise, Lima was to manufacture the neck portion in varying specified sizes. Id. Lima was also to "manufacture the Components […] in accordance with the applicable current Purchaser approved drawings […] and the applicable delivery specifications." Id. at 5.

The Supply Agreement specified other details pertinent to the question before the Court, including that Lima granted to DJO a non-exclusive license and right to use Lima's trademarks in marketing materials. Id. at 14. Title to the Components passed to DJO at the place of shipment, and DJO assumed all risk of damage to such Components. Id. at 9. Accordingly, the agreement provided that all Components received by DJO were "subject to inspection and performance testing, if any, to determine the Components'… conformity to the … Specifications." Id., Section 4.01.

The Supply Agreement also set forth terms to govern regulatory matters related to the Components. Id. at 10. Both Lima and DJO agreed to "comply in all material respects with all applicable Laws that pertain[ed] to the activities for which Seller and Purchaser [were] each responsible under [the] Agreement." Id. However, the agreement also assigned DJO the responsibility for obtaining, in DJO's name, all regulatory certifications to allow "Purchaser and Seller to sell the Product and all Components" in the United States, "including all FDA clearance letters and 510(k)s."[2] Id. The agreement required Lima to "assist" DJO in obtaining the certifications by providing declarations of

[2] Product is defined as "any part of a joint prosthesis system designed, developed, manufactured, marketed or distributed by Purchaser that mates with the Components." (Dkt. 103-3 at 28.)

conformity and certification, technical files, licenses and registrations, and specifications. Id. Lima agreed also to provide DJO with immediate notice should it obtain information that indicated a material defect that could affect the safety or efficacy of any of the Components. Id.

DJO further agreed to comply with the FDA's Medical Device Reporting requirements, as set forth in 21 C.F.R., Part 803. Id. Again, Lima agreed to assist DJO by providing information necessary for compliance with the reporting requirements. Id. Finally, among these terms of the agreement related to regulatory responsibilities, Lima and DJO both agreed to submit to the United States Food and Drug Association (FDA) "any necessary reports of removals, corrections, or other field actions" respecting "the Product and Product's Labeling" and "the Components." Id. at 12.

2. DJO's 510(k) Application to the FDA

With the Supply Agreement in place, on July 31, 2009, DJO submitted a 510(k) application to the FDA. (Dkt. 113-2.) The application requested FDA clearance for use of a new hip stem. Id. at 2. In the application, "DJO Surgical" was identified as manufacturer of the "DJO Modular Revision Femoral Hip Stem," which the application described as being "made up of a modular stem coupled with a proper neck by means of a 'Morse' taper stabilized during the implantation phase by a safety screw." Id. DJO's application referred to the three parts as a "system." Id.

Of particular note, DJO's 510(k) application included a section titled, "Packaging and Sterilization." Id. at 8. Therein, DJO described the process by which it would

package, label, and sterilize the parts of the hip system to ready them for commercial distribution. Id. The process involved DJO completing the following; First, DJO placed each component into multiple polyethylene peel pouches. Id. Next, DJO air vacuumed and heat sealed each pouch. Id. DJO then placed the components in a container, separated by protective packaging, including die cut paperboard and foam pads to restrict movement. Id. DJO affixed product labeling to each portion of the packaging, from the innermost pouch to the outer container. Id. DJO included its Instructions for Use and tracking labels inside the carton. Id. Next, DJO shrink-wrapped "[t]he entire packaged assembly." Id. According to the application, DJO sterilized the product "after the implant [was] packaged and labeled." Id. The labels affixed by DJO stated that all of the metal components had a six (6) year expiration date.[3] Id. In March of 2010, the FDA approved DJO's application for the "DJO Surgical Revision Femoral Hip System."[4] (Dkt. 105-4.)

A. Surgical Brochures and Instructions for Use

Consistent with its regulatory obligations as the manufacturer of record, DJO drafted the surgical technique brochures and Instructions for Use (IFU) that accompanied the DJO Surgical Revision Femoral Hip System when it was marketed and sold in the United States. (Brochure, Dkt. 113-2 at 8); (DJO IFU, Dkt. 104-10.) Also consistent with

[3] According to FDA guidance, "final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR 801 before introducing a medical device to interstate commerce." (U.S. DEPT. OF HEALTH AND HUMAN SERV., FOOD AND DRUG ADMIN., GUIDANCE FOR INDUSTRY AND FDA STAFF (2007), Dkt. 104-9 at 15 n. 8.)

[4] Within its letter approving the application, the FDA directed DJO to existing major regulations affecting the device. (C.F.R., Title 21, pts. 800 to 898.) The letter also included a paragraph regarding device labeling regulation. (Dkt. 105-4 at 2-3.)

the Supply Agreement, Lima provided DJO technical information to draft the documents. Notably, in 2010, Lima sent DJO the IFU Lima produced and included with the modular revision femoral hip stem systems for which Lima obtained license to prepare, market, and sell throughout Europe. (Lima's IFU, Dkt. 105-6 at 3.)

Consideration of the content of the brochure and IFU is also helpful to the Court's determination of whether the BAAA applies to preempt Plaintiffs' claims against Lima. For example, DJO Surgical's name and address appear on the front and final pages of its surgical technique brochure. (Dkt. 113-4 at 4; 16.) Also on the front page is the following language: "This brochure is presented to demonstrate a surgical technique. DJO Surgical, as the manufacturer of this device, does not practice medicine and cannot recommend this or any other surgical technique for [unreadable]." Id. at 4 (emphasis added). However, the brochure also referred to the hip as the "Lima Modular Revision Hip" on the top of the second page and throughout the document. Id. at 5-16. DJO's use of Lima's name in the brochure is consistent with the limited license granted by Lima in the Supply Agreement. (See Dkt. 103-3 at 14.)

As with the surgical brochure, DJO Surgical's name appears throughout its Instructions for Use. (Dkts. 104-10; 104-11.) The IFU describe the product as the "Modular Revision Hip Stem" and the "DJO Modular Revision hip stem" and indicate that the "stem can be used with either DJO Surgical CoCr or Ceramic femoral heads." (Dkt. 104-10 at 2.) Consistent with DJO's 510(k) application to the FDA, the IFU indicate that the "DJO Surgical Modular Revision Hip Stems are supplied sterile…" and

that sterilization "is performed by gamma radiation…." Id. The IFU state that "DJO Surgical has validated sterilization cycle data on file." Id. at 4. Finally, and notably, the DJO IFU state that, "DJO Surgical Hip systems are manufactured by Encore Medical, L.P. 9800 Metric Blvd., Austin, TX 78758 USA (Made in the USA)." Id.

DISCUSSION

1. Summary Judgment under the Biomaterials Access Assurance Act

In 1998, Congress enacted the Biomaterials Assurance Act (BAAA) with the aim of assuring "the continued supply of materials for lifesaving medical devices" through provisions insulating the suppliers of raw materials or component parts of medical devices from litigation. 21 U.S.C. § 1601 et seq. The Act applies to "any civil action brought by a claimant, whether in a Federal or State court, on the basis of any legal theory, for harm allegedly caused, directly or indirectly, by an implant." 21 U.S.C. § 1603(b)(1). In effect, the BAAA "provides immunity to biomaterials suppliers who provide component parts to manufacturers of medical devices." Wilson v. Ethicon Women's Health & Urology, WL 1900852, at *2 (S.D.W. Va. May 13, 2016).

The BAAA permits a biomaterials supplier to file a motion for summary judgment on the basis that the claims against it are preempted by the Act. 21 U.S.C. § 1605. A court must grant summary judgment if there are no genuine issues of material fact as to (1) whether the biomaterials supplier acted as manufacturer of the implant; acted as seller of the implant; or furnished raw materials or component parts for the implant that failed to meet applicable contractual requirements or specifications; or (2) whether the

biomaterials supplier can be considered the manufacturer of the implant that caused harm to a claimant because: it was required to register with the Secretary of Health and Human Services; or was the subject of a declaration issued by the Secretary that stated the supplier, with respect to the implant, was required to register or to include the implant on the list of devices and failed to do so. Id. at § 1604(a-b).

A. Preemption under the BAAA

Lima argues Plaintiffs' claims are pre-empted by the BAAA, because Lima was a biomaterials supplier of component parts for the DJO Surgical Revision Femoral Hip System. Plaintiffs assert Lima was the manufacturer of the hip system and that DJO was merely a distributor or seller. Plaintiffs assert that DJO is an orthopedic medical device company that provides hip, knee, and shoulder devices. (Plaintiffs' SOF, Dkt. 112-1(emphasis added)). Plaintiffs point to a press release jointly issued by DJO and Lima in announcing the partnership formalized in the 2009 Supply Agreement. The release described a "strategic partnership" allowing "Lima Corporate to distribute select DJO Surgical products in Europe, while Lima Corporate will provide products for sale in the US through DJO Surgical." (Dkt. 112-1 at 2.)

In turn, Lima argues DJO is an orthopedic medical device company that manufactures hip, knee, and shoulder devices. (Dkt. 104-2 at 2 (emphasis added)). Lima points to the terms of the Supply Agreement whereby Lima agreed to manufacture and

deliver component parts "to be incorporated into a DJO prosthesis system (ultimately cleared by the FDA as the 'DJO Modular Hip Revision System')."[5] Id.

The BAAA defines a "biomaterials supplier" as "an entity that directly or indirectly supplies a component part […] for use in the manufacture of an implant." 21 U.S.C. § 1602(1)(A). For this definition to apply to Lima, the Court must find that there is no genuine issue of material fact that the hip stem and neck were two separate component parts of the hip system implanted in Mr. Connell.[6] (Dkt. 104-1 at 8.)

Under the BAAA, a "component part" is "a manufactured piece of an implant." 21 U.S.C. § 1602(3)(A). An "implant" is "a medical device that is intended by the manufacturer of the device to be placed into a surgically or naturally formed or existing cavity of the body for a period of at least 30 days." Id. at 1602(5)(A)(i). And a "manufacturer" is "any person who, with respect to an implant is engaged in the manufacture, preparation, propagation, compounding, or processing of the implant; and is required to register with the Secretary [of Health and Human Services]" … "and include the implant on a list of devices filed with the Secretary." Id. at 1602(6). Further, under the Act, the term "manufacture, preparation, propagation, compounding, or processing"

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[5] In its March 2010 510(k) application approval letter, the FDA identified the system as the "DJO Surgical Revision Femoral Hip System." (Dkt. 105-4.) This specific language is not used throughout the briefing or even throughout the record evidence. However, the Court finds the variations result in slight differences that are not material to disposition of the motion.

[6] At the January 22, 2019 hearing on the motions, Plaintiffs reiterated the argument that, if the Court found that Lima is a manufacturer under the BAAA, such finding would preclude the Court finding Lima was a biomaterials supplier under the BAAA. However, Plaintiffs conceded that, if Lima made and supplied only one component of the hip system, for example just the head, or just the stem, Lima would, in fact, be a biomaterials supplier for purposes of the BAAA and Plaintiffs could not proceed in asserting their claims in this action.

of the implant, "shall include" entities engaged in "repackaging or otherwise changing the container, wrapper, or labeling of any […] device package in furtherance of the distribution of the […] device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user." 21 U.S.C. § 360(a)(1).

The distinction between component parts and biomaterials suppliers and implants and manufacturers has been discussed by federal courts throughout the country. For instance, a court in the Eighth Circuit found that "a Section 510(k) device… is an 'implant' and is therefore governed by the BAAA." Daley v. Smith & Nephew, Inc., 321 F. Supp.3d 891, 897-98 (E.D. Wis. 2018).[7] A court in the Third Circuit found that, when a component is unable to be implanted into a human being without additional components, manufacturing steps, and quality steps, it is not an implant for purposes of the BAAA. Id. at 896-97; Mattern v. Biomet, Inc., 2013 WL 1314695 (N.D.J. March 29, 2013). Additionally, a court in the Tenth Circuit found that, when a company supplies a component for a hip system, such as a finished femoral head, but does not supply all of the components, the company is likely a biomaterials supplier and not a manufacturer. Whaley v. Morgan Advanced Ceramics, Ltd., 2008 WL 901523 (D. Col., March 31, 2008). The court held this is true even if the company that manufactures the component

[7] Defendant company machined femoral neck components pursuant to a contract with another company. The neck components be fashioned from a raw titanium, as specified by the other company per the contract terms. 321 F. Supp.3d at 897-98 The court found the defendant company qualified as a biomaterials supplier because the facts showed the machined necks were not completed medical devices as they could not be implanted into a human being without additional components and numerous other manufacturing steps and quality checks performed by others. Id. at 898.

also helps with the premarket approval process by providing necessary information yet does not conduct the regulatory submissions itself. Id.

This guiding case law and the following facts support the finding that Lima was a biomaterials supplier of component parts for the DJO Surgical Revision Femoral Hip System. Lima provided two pieces of the three-part hip system—a distal stem and a femoral neck. Lima did not manufacture or provide the safety screw. Lima fashioned the stem and the neck out of a raw titanium. Lima also provided DJO with information necessary for DJO to complete the FDA premarket approval process but did not conduct any regulatory submissions itself.

A close review of the Supply Agreement's terms and conditions shows that Lima was characterized as a seller of the component parts that would be used by DJO in joint prosthesis systems that DJO owned, licensed, marketed, and sold throughout the United States. For example, as set forth in the facts above, DJO is defined in the agreement as the Purchaser—an entity "engaged in the design, development, manufacturing, distribution and sale of, among other things, joint prosthesis systems." (Dkt. 103-3 at 4.) Lima, on the other hand, is described as the Seller—an entity "engaged in the design, development, manufacture, distribution and sale of, among other things, the Components … for use in, among other things, total joint replacement systems." Id.

According to the Supply Agreement, Lima was responsible for manufacturing the Components in accordance with specification drawings approved by DJO. Title to the Components passed to DJO at the place of shipment and DJO was responsible for

inspecting and conducting performance testing to ensure the Components were in conformity with its specifications. Furthermore, under the agreement DJO had sole responsibility for obtaining all FDA clearances to sell its products in the United States. Relatedly, DJO identified and held itself out as the manufacturer of the "DJO Modular Revision Femoral Hip Stem" in its 510(k) application to the FDA. (Dkt. 113-2.) Lima's name does not appear anywhere within the application. In the application, DJO described the stem as being composed of three parts—a stem, a neck, and a safety screw.

Additionally, undisputed facts show that, when DJO received the two pieces from Lima, they were not yet ready for implantation into a human being. First, the pieces underwent inspection by DJO. Second, the pieces were packaged by DJO to prevent damage while in transit and storage. Third, the pieces were labeled with DJO-specific product numbers that corresponded to the licensure DJO obtained from the FDA. Fourth and finally, DJO performed sterilization of each component prior to final packaging and marking the system with an expiration date.

Part and parcel to readying the components of the hip system for human implantation was including the FDA-mandated Instructions for Use. The IFU included with the hip stem implanted in Mr. Connell were drafted by DJO. In content, the IFU state that DJO Surgical was the manufacturer of the hip system and should be contacted in the event of any questions, including those regarding its labeling or sterilization.

In sum, when the distal stem and femoral neck arrived from Italy in Austin, Texas, at DJO's facility, the parts were not ready for implantation into a human being—a crucial

characteristic of an implant under the BAAA. The two pieces supplied by Lima, though integral, were not yet an implant. As fully set forth above, DJO, as the FDA-approved manufacturer of the "DJO Surgical Revision Hip System" performed the numerous additional steps necessary to ready all three components of the hip system for commercial distribution. Plaintiffs have failed to present evidence that raises a genuine issue of material fact as to that conclusion. Therefore, for purposes of the BAAA, these undisputed facts lead the Court to conclude that Lima was a biomaterials supplier of components parts used by DJO for its Revision Femoral Hip System.

The inquiry does not end here, however, as it is possible that one of the exceptions to the BAAA's shield of liability for biomaterial suppliers applies to Lima. As set forth above, Plaintiffs' product liability claims are not pre-empted by the BAAA if Lima acted (1) as manufacturer of the implant; (2) as seller of the implant; or (3) furnished raw materials or component parts for the implant that failed to meet applicable contractual requirements or specifications. 21 U.S.C. § 1604(a). Thus, the Court must determine whether a genuine issue of material fact exists regarding one or more of these three exception categories.[8]

First, there is no evidence showing or supporting the conclusion that Lima was the seller of Mr. Connell's implant. Rather, undisputed facts show Lima did not hold title to the modular hip system implanted in Mr. Connell, nor did Lima act under contract as a

[8] Of note, Plaintiffs do not provide argument regarding whether Lima, as a biomaterials supplier, acted as seller of the implant or failed to meet applicable contract requirements or specifications. (See Memorandum in Opposition, Dkt. 112 at 3-11.)

seller, or arrange transfer of the implant directly to St. Alphonsus or Mr. Connell. See 21 U.S.C. § 1604(c). Therefore, no genuine issue has been raised that would support the conclusion Lima acted as seller of the implant.

Second, there is no evidence showing or supporting the conclusion the component parts provided by Lima to DJO failed to meet specifications of the 2009 Supply Agreement. Rather, Lima provides evidence in the form of quality assurance records from its factory that no abnormalities were noted for the production lot of stems including the stem eventually implanted in Mr. Connell. There is also no evidence that DJO's inspection upon receipt noted any deviation or that the stems in the shipment failed to meet the specifications set in the Supply Agreement. Plaintiffs have failed to raise conflicting evidence as to these facts. Therefore, no genuine issue has been raised that would support the conclusion that Lima failed to meet applicable contractual requirements or specifications.

As such, the Court's final inquiry is whether Lima, as a biomaterials supplier, may nevertheless be considered the manufacturer of the implant. See 21 U.S.C. § 1604(a)(1). Under the BAAA, this exclusion applies only in the three situations. First, if Lima registered or was required to register with the Secretary of Health and Human Services and included or was required to include the implant on a list of devices filed with the Secretary. Id. at § 1604(b)(2)(A)(i-ii). Second, if Lima was subject to a declaration issued by the Secretary that stated Lima was required to so register and list the implant but failed

to do so. Id. at § 1604(b)(2)(B)(i-ii). Third, if Lima was related by common ownership or control to an entity meeting the requirements set forth in Section 1604(A) or (B).

Plaintiffs do not assert that any of these situations apply to exclude Lima from the BAAA's preemption protections for biomaterials suppliers. (See Plaintiffs' Memorandum in Opposition, Dkt. 112 at 10-11.) Lima, however, states it was neither required to register with the Secretary, nor was it ever the subject of an independent finding by the Secretary that it was required to register. See 21 U.S.C. § 1604(3). Lima asserts that it was not required to register with the Secretary because the components were not ready to be used as they were not "packaged or labeled for commercial distribution" when shipped to DJO (citing 21 C.F.R. 807.65(a) and 807.20(a)(6)).

After careful review of the record, the Court finds no facts that dispute or introduce any doubt as to Lima's representations regarding the inapplicability of this exemption. Therefore, the Court finds the BAAA applies to preempt Plaintiffs' product liability claims and will grant Lima's motion summary judgment.

CONCLUSION

For the reasons outlined herein, the Court will grant Lima's motion for summary judgment based on its finding that, as a matter of law, Lima Corporate, S.p.a. was in this case a biomaterials supplier of component parts under the BAAA. As such, the five remaining motions must be denied as moot.

ORDER

NOW THEREFORE IT IS HEREBY ORDERED:

1) Defendants' Motion for Summary Judgment (Dkt. 104) is **GRANTED**.

2) Defendants' Motion to Exclude Sharlin "Rebuttal" (Dkt. 97) is **DENIED as MOOT**.

3) Defendants' Motion to Exclude Burns Explant Evidence (Dkt. 106) is **DENIED as MOOT**.

4) Plaintiffs' Motion for Partial Summary Judgment (Dkt. 98) is **DENIED as MOOT**.

5) Plaintiffs' Motion to Amend (Dkt. 99) is **DENIED as MOOT**.

6) Plaintiffs' Motion to Exclude Expert Testimony of Dr. Timothy Wright (Dkt. 73) is **DENIED as MOOT**.

DATED: January 30, 2019

Candy W. Dale
U.S. Magistrate Judge